

FOLLOW-ON DOCUMENT INDEX SHEET



A DOCPHOENIX

INCOMING

ACPA	Continuing Prosecution Application
AP.B	Appeal Brief
C680	Request for Corrected Notice/Allowance
C.AD	Change of Address
CFILE	Request for Corrected Filing Receipt
COCIN	Papers filed re Certificate of Corrections
CRFD	Computer Readable Form Defective
CRFE	Computer Readable Form 'ENTERED'
EABN	Request for Express Abandonment
ELC.	Response to Election/Restriction
IFEE	Issue Fee Transmittal PTOL 85 B
IRFND	Refund Request
L_RIN	Any Incoming to L&R
N417	Copy of EFS Receipt Acknowledgement
N/AP	Notice of Appeal
PA..	Change in Power of Attorney
PC/I	Power to Make Copies or to Inspect
PEF.	Pre-Exam Formalities Response
PEFRREISS	Pre-Exam Formalities Reissue Response
PEFRSEQ	Pre-Exam Formalities Sequence Reply

INCOMING

IET	MISS Incoming Letter
MIS	Miscellaneous Internal Document
PGEA	Req Express Aband to avoid Publication
PGA9	Req for Corrected Pat App Publication
PGREF	Req for Refund of Publication Fee Paid
PROTEST	Protest Documents Filed by 3 rd Party
PROTRANS	Translation of Provisional in Nonprovisional
REM	Applicant Remarks in Amendment
RESC	Rescind Non-Publication Request
RETRMAIL	Mailed Returned by Post Office
XT/ I	Extension of Time filed separate

APPL PARTS

371P	PCT Papers in a 371 Application
A...	Amendment Including Elections
A.NE	After Final Amendment
A.PE	Preliminary Amendment
ABST	Abstract
ADS	Application Data Sheet
AF/D	Affidavit or Exhibit Received
APPENDIX	Appendix

APPL PARTS

ARTIFACT	Artifact
CLM	Claim
COMPUTER	Computer Program Listing
CRFL	CRF Transfer Request
CRFS	Computer Readable Form Statement
DIST	Terminal Disclaimer Filed
DRW	Drawings
FOR	Foreign Reference
FRPR	Foreign Priority Papers
IDS	IDS Including 1449
NPL	Non-Patent Literature
OATH	Oath or Declaration
PET.	Petition
PGPUB DRAWINGS	Box PG Pub Drawings
SEQLIST	Sequence Listing
SPEC	Specification
SPEC NO	Specification Not in English

Office Action Summary	Application No.	Applicant(s)
	10/768,335	PENDHARKAR ET AL.
	Examiner	Art Unit
	Anand U Desai, Ph.D.	1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 30 January 2004.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-63 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) _____ is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) 1-63 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-19, drawn to a hemostatic composition, classified in class 514, subclass 54.
 - II. Claims 20-34, drawn to a method for making a substantially homogenous hemostatic composition, classified in class 435, subclass 13.
 - III. Claims 35-49, drawn to a medical device suitable for applying a flow able hemostatic composition, classified in class 606, subclass 1.
 - IV. Claims 50-63, drawn to a method for making a medical device suitable for applying a flow able hemostatic composition, classified in class 523, subclass 113.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions II and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the method of Invention II can be used to make a materially different product. The mixing of a liquid, with an insoluble polymer, and a gas can produce a slow release pharmaceutical.
3. Inventions IV and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be

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made by another and materially different process (MPEP § 806.05(f)). In the instant case a medical device to deliver a hemostatic composition can be made by a different process, such as the process of manufacturing, Duploject® from Baxter, Inc.

4. Inventions I, III, and, IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the hemostatic composition of Invention I is different in structure and function to the medical device of Invention III, and the composition of Invention I is not used in the method of Invention IV.

5. Inventions II, and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the method of making a hemostatic composition in Invention II has a different function from the medical device of Invention III.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to**

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final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined.

See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

8. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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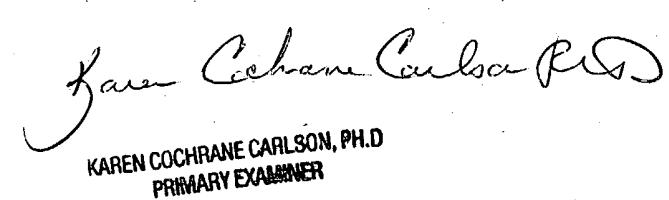
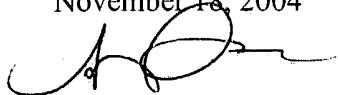
9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anand U Desai, Ph.D. whose telephone number is (571) 272-0947. The examiner can normally be reached on Monday - Friday 9:00 a.m. - 5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (517) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

November 18, 2004



Karen Cochrane Carlson, Ph.D.
KAREN COCHRANE CARLSON, PH.D.
PRIMARY EXAMINER